

Message

From: Norris, Anne [Anne.Norris@fda.hhs.gov]
Sent: 9/27/2017 9:20:53 PM
To: Strauss, Linda [Strauss.Linda@epa.gov]
CC: StClair, Christie [StClair.Christie@epa.gov]; Valentine, Julia [Valentine.Julia@epa.gov]; Daguillard, Robert [Daguillard.Robert@epa.gov]; Putnam, Juli [JuliAnn.Putnam@fda.hhs.gov]; Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]; Flamm, Eric [Eric.Flamm@fda.hhs.gov]; Epstein, Laura [Laura.Epstein@fda.hhs.gov]; McNally, Robert [McNally.Robert@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Subject: RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Oh good, thanks so much. Please call when you can.

Anne

From: Strauss, Linda [mailto:Strauss.Linda@epa.gov]
Sent: Wednesday, September 27, 2017 5:15 PM
To: Norris, Anne
Cc: StClair, Christie; Valentine, Julia; Daguillard, Robert; Putnam, Juli; Nalubola, Ritu; Flamm, Eric; Epstein, Laura; McNally, Robert; Milewski, Elizabeth; Mendelsohn, Mike
Subject: Re: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

I'll be back in my office in 10 minutes.

Sent from my iPhone

On Sep 27, 2017, at 5:03 PM, Norris, Anne <Anne.Norris@fda.hhs.gov> wrote:

Looping in Bob, Elizabeth, and Mike now because I tried calling all four of the EPA communications contacts we have on this issue and can't reach anyone. Normally, I'd wait until the morning and try again, but given the time constraints, we just need to ensure that someone from EPA communications is handling this. Linda's voicemail said she's [Ex. 6 - Personal Privacy] so hoping that if she's already [Ex. 6 - Personal Privacy] that you may be able to suggest who else we can contact.

Thanks,
Anne

From: Norris, Anne
Sent: Wednesday, September 27, 2017 4:42 PM
To: Strauss, Linda; StClair, Christie; Valentine, Julia; 'Daguillard, Robert'; Putnam, Juli
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura
Subject: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK
Importance: High

Hi Linda,

We just learned that this final guidance is on an EXTREMELY fast trajectory and we're almost certainly going to be announcing by this Friday (9/29). Unfortunately, our communications documents are still in clearance and it would be premature to send them to you in case edits still need to be made. At this point, we should be able to share tomorrow, but it's unclear at what time.

We will share our CVM Update and Responsive QAs at the earliest point possible; however, if you wait until after you view our comms to start developing your QAs or talking points, you won't be allowing

yourselves adequate time. Additionally, our responsive QAs are primarily geared toward addressing the questions that the FDA anticipates getting, which won't be very helpful for EPA's needs when it comes to questions that will be directed to EPA from media and stakeholders. Of particular sensitivity right now is the issue of mosquitoes and hurricane relief.

Given the short timeframe, we would strongly suggest that you and your team consult with the EPA policy team working on this issue to get their thoughts on what issues/questions they expect to arise and how they would advise you to handle them. My understanding is that those people are Bob McNally, Elizabeth Milewski, and Mike Mendelsohn.

As Juli had previously mentioned, some examples of the types of questions you might get could be things like:

- What further regulation will the sponsor have to go through to conduct field trials in jurisdictions within the US or to get a commercial approval for the mosquitoes? Will EPA rely on the data the sponsor already provided to the FDA? How long will the process take?
- Do you have any applications/permits/whatever the correct terminology is from Oxitec in house that you are currently reviewing?
- Does the EPA have comment on FDA's guidance? Will this delay the approval/permitting of Oxitec's GE mosquitoes to Hurricane-stricken areas?

Please keep in touch with questions and concerns – feel free to call me anytime at 240-402-0132. We'll reach out tomorrow about the status of our communications and to set up a call with you, if needed.

Thanks,
Anne

Anne Norris
Health Communications Specialist

Strategic Communications & Public Engagement Team
Office of Foods and Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
M: 240-704-0579
Anne.Norris@fda.hhs.gov

<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>